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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,201	01/22/2004	Thomas Boren	0825-0176P	3104

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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,201	BOREN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/8/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,19 and 22-30* is/are pending in the application.

4a) Of the above claim(s) *1,9, 10-12,13,14-15, and 22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8,16,19 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 19, 22-30 are pending.
Claims 2-8, 16, 19, 27-30 are under consideration.
Claims 17-18 and 20-21 have been canceled.
Claims 1,9, 10-12,13,14-15, and 22-26 stand withdrawn from consideration.
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections/Rejections Withdrawn

1. Claims 5, 8, 16 and 19 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been obviated by amending the claims to no longer recite the phrase "or homologues thereof" .
2. Claim 16 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been obviated by amending the claims because claim 16 has been amended to recite additional components not presented in claim 3,
3. Claim 19 de objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been obviated by amending claim 19 to recite additional components not presented in claim 6.
4. Claims 6 and 19 objected to because of the following informalities has been obviated by amending the claims to no longer recite the term "nonospecific".
5. Claims 6 and 19 a objected to because of the following informalities has been obviated by amending the claims to no longer recite the term "HipC"
6. Claims 4-5, 7-8 and 29-30 objected to because of the following informalities has been obviated by amending the claims to recite the phrase ---The isolated-----.
7. Claims 5 and 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, based upon the recitation of the phrase "or homologues thereof" has been obviated by deleting this phrase from the claims.
8. Double Patenting Withdrawn in light of the amendment of claims 27 and 29; and claims 28 and 30 to recite a different combination of claim limitations. See MPEP § 706.03(k).
9. 35 USC § 112, first paragraph Claims 3-5 and 6-8, 16, 19, 27-30 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reciting the phrase "or homologues thereof" is herein withdrawn in light of the deletion of this phrase from the claims.

Rejections Maintained/ Response to Arguments

1. Applicant's arguments filed August 8, 2006 have been fully considered but they are not persuasive.

Response to Amendment/Declaration under 37 CFR 1.132

2. The Declaration of Lennart Hammerstron, Professor of Immunology under 37 CFR 1.132 filed August 8, 2006 is insufficient to overcome the rejection of claims 3-8, 16, 19 and new claims 27-30 under 35 U.S.C. 102(b) based upon Durrant et al (1993) because the Declaration traverses the rejection by focusing on the evidence provided by Essery et al as set forth in the last Office action, and not Durrant et al.

Professor Hammerstron asserts that "the Examiner says that Essery et al. show that an anti-idiotypic antibody that recognizes the Lewis B antigen structure would bind to the BabA protein (which itself binds to the Lewis B antigen)".

3. It is the position of the examiner that the reference applied against the claims is Durrant et al (1993) . At no time did the Examiner state that the anti-idiotypic antibody of Essery et al "recognizes the Lewis B antigen structure" but cited Essery et al to provide evidence that Helicobacter pylori would bind to anti-id antibodies that present Lewis antigens, and also stated that the Lewis A anti-id antibody of Essery was also immunoreactive with anti-Lewis B antibodies (see page 19, col. 2, paragraph 1) showing conserved Lewis antigen structures between Lewis antigens A and B to be recognized by antibodies, the conserved Lewis antigen epitope being presented by the Anti-Id antibody. Professor Hammerstron's characterization of Durrant et al, by traversing Essery et al, a reference not applied to the claims, is not directed to the reference applied against the

claims. No evidence has been provided to show that the anti-id Lewis B antibody of Durrant et al, which presents the Lewis B antigen epitope structure, would not be bound by Helicobacter pylori strains and species that bind to Lewis B antigens.

Durrant et al produced a monospecific polyclonal antiserum through affinity purifying the antibody by column chromatography (see page 648, "Production and purification of rat anti-C14 ID antibody preparation"). The anti-Id antibody presented a positional isomer of the Lewis b hapten; the anti-ID presented the Lewis b antigen equally as well as Lewis y (see Durrant et al, page 654, first paragraph). Durrant et al still anticipates the instantly claimed invention as now claimed.

10. Professor Hammarstrom address the prior art rejection over claims 3-8, 16,19, 27-30 under 35 U.S.C. 102(b) as being anticipated by Uemura et al (US Pat 5,258,177) in light of evidence provided by Boren et al (1995, reference of record) by stating that "the claims do not recite that the specific binding is carried out by the hypervariable region". Stating this fact is superfluous".

11. The examiner agrees that the claims need not recite that the Lewis B antigen is bound by the hypervariable region of the claimed antibodies, but this phrase could obviate the Uemura et al reference whose composition of antibodies/immunoglobulin bind to Lewis B antigen by an other region. The monospecific compositions of Uemura et al obtained from human colostrums defined to be sIgA, inherently anticipates the instantly claimed invention in light of evidence provided by Boren et al (1995, reference of record, page 32, col. 1-2) who show human colostrum IgA to specifically bind to

Helicobacter pylori blood group binding antigen (Bab, Lewis b antigen being present on the surface of sIgA of human colostrum).

12. The obviousness rejection of claim 2 rejected under 35 U.S.C. 103(a) as being obvious over Boren et al (reference of record, 1995) in view of Foster et al (US Pat. 4,444, 879, reference of record) is addressed by Professor Hammarstrom by stating that "the invention in application 10/766,201, which claims an antibody preparation which is dependent on the antigen specific binding properties of the antibody itself. That is, normal antibodies that demonstrate binding properties due to the variable domains of the antibody."

13. It is the position of the examiner that Professor Hammarstrom's statements are not commensurate in scope with the instantly claimed invention which must only evidence the functional characteristics claimed, the claimed compositions/preparation must achieve these functional requirements but are not so claimed as requiring the binding to be through the variable domains, but the scope of the claims include any region of the antibody/immunoglobulin composition/preparation that specifically bind to BabA protein, wherein the antibodies/immunoglobulin of Boren et al specifically present/comprise Lewis B antigen. The human colostrum IgA composition/preparation specifically bind to Helicobacter pylori blood group binding antigen (Bab, Lewis b antigen being present on the surface of sIgA of human colostrum), and specifically bind to BabA (see page 32, col. 1-2) and therefore meet the functional requirements of the claimed invention. Boren et al utilized the composition/preparation of human colostrums IgA to specifically bind to Helicobacter pylori BabA antigen in a sample.

14. The claimed kit, of instant claim 2, may be used in a method of detecting antigen in a sample, or to determining binding specificity of BabA antigen or for any other use such as affinity chromatography for purifying Lewis B antigen. A recited intended use of a kit does not define over the prior art composition that was used in an immunoassay method to show the formation of BabA/immunoglobulin complexes, wherein binding between BabA and human antibodies/immunoglobulin compositions/preparations was determined/detected. What is now claimed in claim 2, is a composition, and not a method. No unexpected results have been presented to obviate the rejection of claim 2 under 35 USC 103 over Boren in view of Foster. The rejection is maintained for reasons of record and responses set forth herein.

15. ***Rejections Maintained Claim Rejections:*** The rejection of claims 3-8, 16, 19 and new claims 27-30 under 35 U.S.C. 102(b) as being anticipated by Durrant et al (1993) is traversed on essentially the same grounds set forth in the Declaration provided by Professor Hammarstrom's

16. Applicant focuses the traversal on a reference not applied against the claims, specifically Essery et al. The Examiner's response to these arguments are set forth above and are incorporated herein by reference. Durrant et al still inherently anticipates the instantly claimed invention as now claimed.

17. ***Claim Rejections - 35 USC § 102 Maintained.*** The rejection of claims 3-8, 16,19, 27-30 under 35 U.S.C. 102(b) as being anticipated by Uemura et al (US Pat 5,258,177) in light of evidence provided by Boren et al (1995, reference of record) is

traversed on the grounds that "[T]hose of skill in the art understand that specific binding is carried out by the antigen binding site of the specific antibody as determined by the sequence of the hypervariable region. If binding of a sugar moiety on some antibodies would confer specific binding, there would be no need for immunization in order to raise anti-BabA specific antibodies.

18. It is the position of the examiner that the instantly claimed products are all product by process claims, and a product with the same or equivalent functional limitations of "BabA protein binds specifically to fucosylated Lewis^B and H-1 blood group antigen-glycoconjugates" would meet the instantly claimed invention. Applicant's traversal is not commensurate in scope with the instantly claimed invention. The binding specificity of BabA protein is directed to fucosylated Lewis^B and H-1 blood group antigens, and the human monospecific collostrum IgA would be specifically bound by BabA protein as the product of Uemura et al presents the fucosylated Lewis^B and H-1 blood epitope to which BabA specifically binds. The instantly claimed products have not been distinguished from the applied prior art.

19. ***Rejection Maintained, Claim Rejections - 35 USC § 103*** Claim 2 rejected under 35 U.S.C. 103(a) as being obvious over Boren et al (reference of record, 1995) in view of Foster et al (US Pat. 4,444, 879, reference of record.) is traversed on the grounds that the combination of Boren et al in view of Foster is impermissible hindsight reconstruction.

20. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on

obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

21. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., antisera or antibody that binds to the adhesion protein via its hypervariable region) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

22. Applicant asserts that the "secretory IgA molecules do not specifically bind adhesion, rather adhesion specifically binds the fucosylated Lewis B antigen presented on the secretory IgA molecule.

23. It is the position of the examiner that the human colostrums secretory IgA and BabA form a specific binding complex based upon the specific molecular structures each molecule presents. The human colostrums secretory IgA successfully eliminated H.pylori attachment to gastric surface mucous cells (see Boren page 32, col. 1, paragraph 3), thus specifically binding to BabA localized on H.pylori membranes.

Boren et al teach, show and provides guidance for the artisan to detect the presence of a Helicobacter pylori blood group binding protein antigen utilizing binding of

colostrums sIgA in a method of detecting the presence or absence of the blood group antigen in the sample.

Foster et al teach the formulation of immunoglobulin/antibody compositions into kit form in an analogous art for the configuring a product for distribution for medical purposes .

It would have been obvious to the person of ordinary skill in the art at the time the invention was made modify the configured composition of Boren et al into kit form as taught by Foster et al because Foster et al teaches kits that comprise immunoglobulin (see Foster et al, col. 15, lines 24-26) preparations and the kit provides immunoglobulin reagents for medical purposes (see Foster et al, col. 5, lines 63-68 and col. 6, lines 1-5).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining kits that comprise a human colostrums IgA immunoglobulin composition that is a monospecific that will bind to Helicobacter pylori BabA antigen because Boren et al teach and show the blood group binding protein to be associated with infection in human gastric mucosa (see figure top of page 32 "adhesion experiments), which was significantly inhibited through binding of secretory IgA isolated from human colostrums. The colostrums IgA eliminated H.pylori attachment to gastric surface mucous cells (see page 32, col. 1, paragraph 3) and was also utilized in determining the presence or absence of Helicobacter pylori in a human tissue sample (see page 32, col. 1, paragraph 1 "Immunohistochemical analyses") in an Helicobacter pylori immunoassay

Boren et al defines and shows colostrums sIgA as a specific Helicobacter pylori BabA detection reagent and Foster et al teach the importance of formulation of test kits

that comprise the necessary reagents so the kits can be readily used by the medical community in detecting/diagnosing the presence or absence of a protein analyte in a biological sample, and Boren et al teaches BabA to be an Helicobacter pylori infection associated protein of the human pathogen. Boren et al in view of Foster et al obviate the instantly claimed invention.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Various references are being cited to show Helicobacter pylori antigen, paralogues of BabA, inactive forms of BabA, and homologs of BabA that comprise SEQ ID NO 5..

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Mark Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
October 12, 2006

MARK NAVARRO
PRIMARY EXAMINER